No. 84-1794 (5)

Supreme Court, U.S.
FILED
AUG 29 1985
JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

October Term, 1984

JOSEPH GERACE, Commissioner, New York Department of Agriculture and Markets, et al.,

Appellants,

v.

GROCERY MANUFACTURERS OF AMERICA, et al.,

Respondents.

On Appeal from the United States Court of Appeals for the Second Circuit

REPLY TO MOTIONS TO AFFIRM

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REPLY TO MOTIONS TO AFFIRM[1]

ARGUMENT

I.

APPELLEES HAVE IGNORED THE IMPACT OF FDA's "IMITATION" RULE UPON THE 1938 ACT's PURPOSE TO ESTABLISH ENFORCIBLE STANDARDS OF IDENTITY.

One of the main purposes of the 1938 Act was to establish enforcible standards of identity. *Federal Security Ad-*

1. This memorandum sets forth New York's reply to both the government's and GMA's Motions to Affirm.

ministrator v. *Quaker Oats Co.*, 318 U.S. 218, 230 (1943). The 1938 Act added 21 USC §343(g).

Pursuant to 21 USC §343(g), a food "purports" to be a standardized food if its physical characteristics simulate the standardized food. *62 Cases of Jam* v. *United States*, 340 U.S. 593, 598 (1951); *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. at 232; *National Nutritional Foods Assn.* v. *Weinberger*, 504 F.2d 761, 774-781 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975). This Court has held that "[t]he statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition." *Quaker Oats Co.*, 318 U.S. at 232. The same conclusion follows *a fortiori* if producers are free to *abstract* ingredients without the "imitation" warning label. The FDA rule does not even require, by analogy to 21 USC §343(c), that a synthetic food label must bear, in type of uniform size and prominence, the word "substitute." FDA requires only that the label bear "a common or usual name" or, in the absence of an existing common or usual name, an "appropriately descriptive term." 21 CFR §101.3(e)(2)(ii). But, FDA has established no "common or usual names" for nutritionally equivalent imitation cheese products. It began, and then terminated, a rulemaking proceeding to establish a common or usual name for such simulated cheeses. 43 Fed. Reg. 42118 (1978).

The net effect of all this transcends a change in the definition of the word "imitation." FDA now has more than 70 standards of identity for cheeses. All require dairy ingredients. 21 CFR §133.102—133.196. All were established after formal rulemaking on a record. 21 U.S.C. §371(e). All these foods can be simulated, and the standard of identity circumvented, merely by the use, somewhere on the label, of an "appropriately descriptive term." 21 CFR §101.3(e)(2)(ii).

II.

APPELLEES HAVE NOT SERIOUSLY ADDRESSED *QUAKER OATS* or *62 CASES OF JAM.*

GMA argues that the holding in *Federal Security Administrator* v. *Quaker Oats Co.,* is limited to instances "where the substitution made the product inferior to the standardized product." (GMA Motion, p. 11). In fact, the farina cereal involved in that case was nutritionally superior to the standardized food, and was in violation of the standard precisely because Quaker Oats had *added* a nutrient (Vitamin C). 318 U.S. at 224. GMA also argues that in *62 Cases of Jam,* this Court emphasized that the imitation product was "inferior." The page of the opinion cited by GMA (340 U.S. at 600), relies upon Sen. Rep. No. 361, 74th Cong., 1st Sess., 8-11, which unequivocally demonstrates Congress' intention to deal with economic inferiority. This is also demonstrated throughout the legislative documents cited by the Court in *Quaker Oats,* 318 U.S. at 230.

The government agencies have attempted to present *62 Cases of Jam* and *Quaker Oats* as nothing more than passive judicial acquiescence in a factually derived administrative policy. (Gov't. Motion, p. 8). In fact, both decisions were adjudications by this Court of the meaning and purpose of an act of Congress. This Court wrote in *62 Cases of Jam:*

> Regard for these [Congressional] purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. (Citation omitted). This is the attitude with which we should approach the *problem of statutory construction* now presented. But our problem is to *construe what Congress has written.* After all, Congress expresses its

> purpose by words. It is for us to ascertain—neither to add nor to subtract, neither to delete nor to distort. 340 U.S. at 596 (Emph. Added).

FDA itself recognized in the rulemaking proceeding that the issue required examination of judicial decisions and discernment of Congressional purpose. 38 Fed. Reg. 2138 (1973). FDA discussed this Court's decisions and "several State court cases in the past 10 years." 38 Fed. Reg. 20702). FDA came to the amazing conclusion that the state court decisions "represent the most current and definitive judicial interpretation of the term 'imitation'." *Id.* Therefore, FDA itself correctly looked to the courts, but then became inexplicably confused as to what court provides the definitive judicial authority on federal statutory construction.

The suggestion that an administrative agency may displace this Court's construction of the statutory meaning and purpose with "an equally reasonable definition" is simply untenable. This Court's decision in *Quaker Oats* and *62 Cases of Jam* were not addressed to policy choices but to "the quintessential judicial function of deciding what a statute means." *Bureau of Alcohol, Tobacco & Firearms* v. *FLRA*, —— U.S. ——, 104 S.Ct. 439, 443-45, n.8 (1983).

The controversy involved in this case requires the exercise of two uniquely judicial functions: (1) The construction of an Act of Congress, and (2) the constitutional review of an act of a state legislature. Both functions are central to "the Judicial power of the United States" which is vested exclusively in the federal courts. U.S. Const., Art. III, Sec. 1. Misplaced emphasis upon the "deference" rule has diverted the lower courts from the uninhibited exercise of their historic Article III functions. It is respectfully submitted that New York should be accorded this Court's plenary review and adjudication of the fundamental issues presented by this case.

III.

CONGRESSIONAL INACTION IS MEANINGLESS BECAUSE FDA ITSELF WAS ENGAGED FOR FIVE YEARS IN A PROCEEDING TO RECONSIDER AND POSSIBLY REVOKE ITS IMITATION REGULATION.

GMA's inference of Congressional acquiescence (GMA Motion, p. 10), in which the Court of Appeals also indulged (J.S. App. 14a-15a), cannot be sustained in the face of the administrative history of FDA's regulation. Less than four months after FDA adopted its imitation regulation, New York challenged the federal statutory basis for the nutritional equivalence rationale and Judge WIENFELD sustained New York in *Swift & Co.* v. *Walkley*, 369 F.Supp. 1198 (S.D.N.Y. 1973). Three years later, FDA was sustained in *Federation of Homemakers* v. *Schmidt*, 539 F.2d 740 (D.C. Cir. 1976).

With judicial authority thus divided, the Commissioner of Food and Drugs announced in October, 1977 his intention to hold hearings on the broad issues of food labeling. 43 Fed. Reg. 25296 (1978). In June, 1978, the FDA announced five "Grass Roots" public hearings to be held jointly with USDA and FTC to hear public opinion on food labeling issues including "Imitation and Substitute Foods." *Id.* FDA solicited public comment on eleven particularized questions, including: "1. What kind of food should be called imitation? 2. What does the word 'imitation' on the food label mean to you?" 43 Fed. Reg. 25304-05 (1978).

In December 1979, the federal agencies announced further public hearings to be held in 1980, extensively summarized comments from the prior hearings, and announced with respect to "imitation" labeling that "even after a long period of study and discussion, the agencies have not yet reached tentative positions," and "in the absence of a tenta-

tive position, the agencies want comments on a number of options." 44 Fed. Reg. 75991 (1979). The five options ranged from "Maintain existing policy" to "Return to pre-1973 policy and expand imitation labeling." 44 Fed. Reg. 76009 (1979). The hearings were held in March, 1980. Meanwhile, the National Milk Producers Federation filed its own independent petition with FDA which requested revision of the "imitation" regulation. 48 Fed. Reg. 37665 (1983).

On August 19, 1983, FDA finally brought to a conclusion its own reconsideration of the "imitation" regulation, announced its intention not to revoke or change the regulation, and simultaneosuly denied the NMPF petition. 48 Fed. Reg. 37665 (1983). Three months later this litigation began. Since FDA was actively reconsidering its own regulation, and the issue was simultaneously being contested in the courts, Congress had no reason to intervene.

Moreover, any inference from mere inaction by Congress has always been treated cautiously by this Court. *Bob Jones University* v. *United States,* 461 U.S. 574, 600 (1983) ("not often a useful guide"); *United States* v. *Rutherford,* 442 U.S. 544, 554 n.10 (1979) ("may not always be realistic to infer approval"). The cases cited by the Court of Appeals all involved something more than mere inaction. *Haig* v. *Agee,* 453 U.S. 280, 300 (1981) ("Here, however, the inference of congressional approval 'is supported by something more than mere congressional inaction'. *Zemel,* 381 U.S. at 11-12") *United States* v. *Rutherford* 442 U.S. 544, 554 n.10 (1979) ("That Congress is aware of the FDA's policy concerning laetrile is evident from Senate Subcommittee hearings on the Commissioner's 1977 ruling.) *Norwegian Nitrogen Co.* v. *United States,* 228 U.S. 294, 313 (1933) ("In the investigation that followed, the procedure and methods of the Commission were thoroughly explored.")

Here, there is no evidence that there was any direct communication with Congress or any committee activity concerning the "imitation" issue.[2] Congressional non-action is consistent with non-awareness. It is equally consistent with a Congressional decision to await the outcome of action by the Executive branch, which was considering repeal, and the Judicial branch, which had rendered divided —and not yet definitive—decisions.

IV.

APPELLEES HAVE DEMONSTRATED NO CONFLICT BETWEEN THE NEW YORK LAW AND FDA'S REGULATION.

The FDA "imitation" regulation does not prohibit the use of an "imitation" label on a nutritionally equivalent synthetic product. 21 CFR §101.3(e). To demonstrate that New York's law conflicts, the government relies upon a sentence from FDA's Notice of Proposed Rulemaking (Gov't. Motion, p. 7), which in fact supports the conclusion that compliance with both is possible. The sentence quoted does not state that FDA intended to restrict the *use* of the term "imitation," but rather "to restrict *required application* of the term 'imitation'...." 38 Fed. Reg. 2138 (1973) (Emph. Added).

FDA explicitly authorized manufacturers and distributors to use an "imitation" label on foods which are not nutritionally inferior. 38 Fed. Reg. 20703, par. 5(a) (1973).

2. In contrast, when in 1967 Congress adopted the Wholesome Meat Act (21 USC §601 *et seq.*) and in 1968 the Poultry Products Inspection Act (21 USC §453), the Committee reports state an explicit intent to adopt verbatim and conform to the labeling provisions of the Food, Drug & Cosmetic Act. At that time, this Court and FDA followed the long-standing ordinary meaning of the imitation labeling language of the law. Sen. Report No. 799; 2 U.S. Code, Cong. & Admin. News (1967), 2188, 2202-03; House Ag. Comm. Report No. 1333; 3 U.S. Code, Cong. & Admin. News (1968) 3426, 3445).

The government's suggestion that compliance with New York's imitation labeling law would violate 21 CFR §101.3 (e)(2) and (3), because it would be "misleading" to the public, amounts to an assertion of fact. It has no evidentiary support in the adjudicative record. This record contains no statement by FDA that it would find that a product which is labeled to comply with New York law is "misleading" and would be deemed misbranded under the federal regulation. FDA's own grass roots hearings on imitation labeling were summarized by FDA as follows:

> Of the 1,350 commenters who addressed the issue of naming imitation and substitute foods, the overwhelming majority (75 percent) said that they should be labeled 'imitation.' Less than one-fifth of the commenters said that such products should be given a new, descriptive name. A few said either approach would be acceptable or that such foods should be given a new name plus the 'imitation' label. 44 Fed. Reg. 76007 (1979).

See also the extensive consumer survey commissioned by the Food and Drug Law Institute and conducted by the Good Housekeeping Institute, which is reported in McNutt, Powers and Sloan, *Consumer Perceptions on Consumer Protection*, 39 Food & Cos. L. J. 86, 94 (1984). See also USDA Marketing Research Report No. 995, *Homemakers Opinions on Dairy Products and Imitation Foods* (May, 1973).

The courts below attempted to resolve the question of conflict on a barren adjudicative record. The government's reliance upon gleanings from the administrative rulemaking record is misplaced.[3] This is a plenary action at law to adjudicate the constitutionality of a State law. The basic

3. FDA's Notice of Proposed Rulemaking gave no indication that FDA intended to *prohibit* the use of the "imitation" label or to preempt state food laws. 38 Fed. Reg. 2138 (1973). Participation in the rulemaking proceeding would have been radically altered by such a notice.

"constitutional facts" must be found by the court based upon the adjudicative record. *Crowell* v. *Benson*, 285 U.S. 22, 56 (1932); *Ohio Valley Water Co.* v. *Ben Avon Borough*, 253 U.S. 287 (1920); *St. Joseph Stock Yards Co.* v. *United States*, 298 U.S. 38 (1936). There has been no judicial inquiry into the compatability of the federal and state regulatory schemes. New York should receive the same kind of particularized evidentiary inquiry and examination which this Court required in *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 53 U.S.L.W. 4612 (June 3, 1985).

V.

THIS COURT HAS NEVER SANCTIONED THE ADOPTION *IN TOTO* OF ANOTHER AGENCY'S DETAILED REGULATIONS BY DICTA IN AN ADJUDICATION.

Both cases cited by the government agencies merely restate the "general proposition" of *Chenery II* that an agency has discretion to evolve general rules by rulemaking or adjudication. *NAACP* v. *FPC*, 425 U.S. 662, 668 (1976). This Court's opinion in *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267 (1974) recognizes that "there may be situations where the [agency's] reliance on adjudication would amount to an abuse of discretion or a violation of the Act . . . ." *Id.* at 294. This is that case. Congress never intended to allow agencies unreviewable discretion to avoid the public notice and participatory requirements of the APA, especially not in circumstances such as this. Here the administrative action directly touches "phases of the lives and health of the people which, in the circumstances of modern industrialism, are largely beyond self-protection." *62 Cases of Jam* v. *United States*, 340 U.S. at 596 (quoting *United States* v. *Dotterweich*, 320 U.S. 277, 280). The rule also drastically infringes the States' interest in " . . . 'the protection of . . . [their] people against fraud and deception in the sale of food products' at retail markets within their borders. (Citations omitted)". *Florida Avocado Growers* v. *Paul*, 373 U.S. 132, 144 (1963).

Finally, the rule is unmistakably legislative in nature. USDA's adoption of the FDA regulation was not simply the formulation of a general rule or policy. It was the adoption of a detailed standard, which itself refers to and incorporates seven other detailed and technical regulations, as follows:

Common or usual name regulations (21 CFR §102.5); standards of identity pursuant to §401 of the Federal Food, Drug and Cosmetic Act (21 USC 341); nutritional quality guidelines pursuant to 21 CFR Part 104; nutrition labeling regulations (21 CFR §101.9); regulations governing foods for special dietary use (21 CFR Part 105); U.S. RDA regulations which set forth detailed mathematical measurements of 19 vitamins, minerals and other food elements, and definition of average "serving" or "portion" set forth in 21 CFR §101.9(b)(1).

If USDA's attempt to "adjudicate" these standards is invalid, USDA is bound by its original, and traditional, imitation regulation which was never repealed and is still in effect. 9 CFR §317.2(j)(l).

Conclusion

For the foregoing reasons, this Court should note probable jurisdiction.

Respectfully submitted,

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August 27, 1985